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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,678	01/23/2001	Axel Ullrich	038602-1082	4384

7590 07/11/2003

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EXAMINER

SPECTOR, LORRAINE

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 07/11/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.



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DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 5/14/03  
 This action is FINAL.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 36-43, 47-52 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) 43 is/are allowed.  
 Claim(s) 36-42, 47-52 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

**Part III: Detailed Office Action**

Applicants response has overcome the objections to the disclosure, abstract and title, the objection to claim 43, and the rejection of claims 36-43 under 35 U.S.C. § 112, second paragraph.

Applicants amendments have overcome the rejection of claims 36, 38 and 40-42 under 35  
5 U.S.C. § 102(e) as being anticipated by Lemischka.

New rejections apply.

**Double Patenting Rejections:**

Claims 36-41 remain rejected under the judicially created doctrine of obviousness-type  
10 double patenting as being unpatentable over claims 1-8 of U.S. Patent Number 5,851,999.

The Examiner notes applicants' request that the above rejection be held in abeyance.  
Applicants are cautioned that any argument of the above rejections should not be delayed; argument  
of the double patenting rejection after prosecution has otherwise concluded will not be considered  
as being timely. The only actions that will be deemed appropriate at such time as claims are found  
15 otherwise allowable will be cancellation of claims or filing of a terminal disclaimer.

**Objections and Rejections under 35 U.S.C. §112:**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

20 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38, 39, 41, 47 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

25 Claim 38 is indefinite because there is an improper Markush grouping; it is not clear how a single vector can simultaneously be a retrovirus, adeno-associated, and a herpes viral vector.

Claim 41 is further indefinite as it is not clear by what means the cell line expresses truncated Flk-1. Such might be a limitation as to the source or type of cell line, might alternatively require the

presence of a second vector, or might be intended to indicate that the single retroviral vector is both expressing protein and producing infectious particles.

Claims 47 and 48 are indefinite because a protein does not conventionally comprise a nucleic acid sequence. In the interest of compact prosecution, the claims will be interpreted as though 5 "comprising" were -encoded by-.

The remaining claims are indefinite for depending from an indefinite claim.

**Rejections Over Prior Art:**

10 The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25 Claims 36-42 and 47-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemischka (U.S. Patent Number 5,185,438) Matthews, Terman, Ullrich, Ueno-1 and Ueno-2 as applied to claims 36-42 in the previous Office action at pages 6-10.

Applicants traversal has been fully considered but is not deemed persuasive. At page 8 of the response, applicants argue that none of the primary references teaches a truncated Flk-1 receptor within the metes and bounds of the claims, and that none of the secondary references teach

relatedness to Flk-1. This argument has been fully considered but is not deemed persuasive because one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The primary references clearly teach 5 the relatedness of Flk-1 to the receptors disclosed by the secondary references.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed 10 invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The Examiner set forth specific reasons for motivation (see page 9 of the previous Office Action), and the expectation for success is derived from the success in the art at making analogous constructions with analogous receptors. Applicants have provided no fact or evidence to the 15 contrary.

**Advisory Information:**

Claim 43 is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office 20 action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the 25 THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

10 If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

15 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

20 Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

25 Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.

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Lorraine Spector  
Lorraine Spector, Ph.D.  
Primary Examiner

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09/766678.2

7/9/03